

Reshma KOTIAN *et al.*,
Serial No. 10/768,348
"Stabilized Paroxetine Formulation"

IN THE CLAIMS

1 to 25 (cancelled)

26. (Amended) A moisture barrier, non-controlled release pharmaceutical excipient solution
5 comprising:

- A) ethylcellulose;
- B) polar solvent;
- C) alcohol; and
- D) a surfactant.

10 27. (Original) The moisture barrier pharmaceutical excipient of claim 26, wherein said surfactant comprises polysorbate 80, and wherein said polysorbate 80 and said ethylcellulose are present in a ratio of approximately 1.00 : 0.165.

28. (Amended) A process for manufacturing a substantially moisture stable, non-controlled release pharmaceutical product, comprising:

- 15 A) mixing ethylcellulose, polar solvent, alcohol and a surfactant to make a moisture barrier, non-controlled release pharmaceutical excipient solution;
- B) mixing a drug substance with said moisture barrier pharmaceutical excipient solution to form substantially moisture stable drug substance;
- C) coating the substantially moisture-resistant drug substance of step B in a
20 pharmaceutically-acceptable coating.

29. (Original) The process of claim 28, wherein said pharmaceutically-acceptable coating comprises a gelatin capsule.

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30. (Original) The process of claim 28, wherein said surfactant comprises polysorbate 80, and wherein said polysorbate 80 and said ethylcellulose are present in a ratio of approximately 1.00 : 0.165.

31. (Original) The process of claim 28, wherein said drug substance comprises paroxetine.

5 32. (Original) The process of claim 3, wherein said surfactant comprises polysorbate 80, and wherein said polysorbate 80 and said ethylcellulose are present in a ratio of approximately 1.00 : 0.165, and wherein said drug substance comprises paroxetine.

33. (Amended) A substantially moisture stable, non-controlled release drug product comprising:

10 A) A substantially moisture stable, non-controlled release core comprising a drug substance, ethylcellulose and a surfactant; and

B) An outer layer surrounding said core, said outer layer comprising a pharmaceutically acceptable material, said outer layer substantially free of said drug substance.

34. (Original) The drug product of claim 33, wherein:

15 A) said surfactant comprises polysorbate 80, and wherein said polysorbate 80 and said ethylcellulose are present in a ratio of approximately 1.00 : 0.165.

35. (Original) The drug product of claim 33, wherein:

A) said drug substance comprises paroxetine.

36. (Original) The drug product of claim 33, wherein:

20 A) said drug substance comprises paroxetine, said surfactant comprises polysorbate 80, and wherein said polysorbate 80 and said ethylcellulose are present in a ratio of approximately 1.00 : 0.165.

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